REMARKS

Claims 23, 28, and 48-67 are pending. Claims 23, 28, 48-67 are rejected under 35 U.S.C. § 112, first paragraph and claims 23 and 28 are rejected under 35 U.S.C. § 112, second paragraph. Claim 23 is objected to. Each of these rejections and this objection are addressed below.

Claim Amendments

Claims 23 and 28 have been amended to recite specific hybridization conditions. Support for this amendment is found, for example, at page 9, line 22. No new matter has been added.

Claim Objection

As requested by the Office, claim 23 has been amended to correct informalities.

Rejections under 35 U.S.C. § 112, first paragraph

Enablement

Claims 23, 28, and 48-67 are rejected for lack of enablement. In particular, the Office asserts that, in the absence of recitation of clear hybridization conditions, one skilled in the art would not recognize sequences falling within the limitations of the claims. Amended claims 23 and 28, from which the other rejected claims depend, now recite particular hybridization conditions. Accordingly, one skilled in the art would be able to readily practice the full scope of the claimed invention and this aspect of the rejection should be withdrawn.

Claims 28 and 56-67 are further rejected for overbreadth. In applying this rejection, the Office asserts that the specification, while enabling for a method of treating allergen-induced

airway hyper responsiveness and asthma, is not enabling for any allergic condition or allergic reaction. Applicants respectfully traverse this rejection.

Applicants submit that the Office has failed to provide adequate support for doubting the inaccuracy of the present disclosure. Because Applicants have provided teachings (discussed in greater detail below) enabling the claimed invention throughout the specification, the burden is on the Examiner to provide evidence or reasoning of the contrary. This burden is set forth in the Guidelines for the Examination of Patent Applications under 35 U.S.C. § 112, first paragraph, "Enablement" requirement, which states:

> A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject manner sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. Assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). As stated by the court, "it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain *why* it doubts the truth of accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go through the trouble and expense of supporting his presumptively accurate disclosure." 439 F.2d at 224, 169 USPQ at 370.

Thus, all that is relevant is whether Applicants' specification teaches one skilled in the art how to carry out the claimed invention without undue experimentation, a requirement which Applicants have satisfied, as described below.

Indeed, Applicants have provided ample and sufficient enabling teachings such that one skilled in the art would be able to practice the claimed invention in the absence of undue experimentation. Methods of producing polypeptides that inhibit IL-13 binding to the IL-13 receptor are provided, for example, at page 9, line 1 through page 12, line 28 and methods for

determining the ability of a polypeptide to inhibit such binding are described, for example, at page 12, line 29 through page 13, line 30. Furthermore, various formulations are provided at page 16, line 9 through page 17, line 29 and routes of administration are taught at page 17, line 30 through page 18, line 31. Thus, relying on the teachings of the specification and routine molecular biology techniques, one skilled in the art would have been able to: 1) produce polypeptides that are encoded by a polynucleotide that hybridizes at 65^0C in 0.1x SSC to the complement of the portion of SEQ ID NO: 3 that encodes about from about amino acid 26 to about amino acid 341 of SEQ ID NO: 4; 2) test the ability of such polypeptides to inhibit binding of IL-13 to the IL-13 receptor; and 3) administer polypeptides identified as having the ability to inhibit binding of IL-13 to the IL-13 receptor to subjects having an allergic condition, atopy, or asthma. Such experiments would not require undue experimentation.

Moreover, the Office maintains that experimental data must be presented for each indication claimed (e.g., atopy) in spite of Applicants' teachings that the claimed method is useful in a murine model of airway hyper responsiveness (AHR). Applicants note, however, that the case law does not support such a requirement. In this regard, the M.P.E.P. clearly states (emphasis added):

> *An applicant need not have actually reduced the invention to practice prior to filing.* In *Gould v. Quigg*, 822 F.2d 1074, 1078, 3 USPQ 2d 1302, 1304 (Fed. Cir. 1987), as of Gould's filing date, no person had built a light amplifier or measured a population inversion in a gas discharge. The Court held that "The mere fact that something has not previously been done clearly is not, in itself, a sufficient basis for rejecting all applications purporting to disclose how to do it." 822 F.2d at 1078, 3 USPQ2d at 1304 (quoting *In re Chilowsky*, 229 F.2d 457, 461, 108 USPQ 321, 325 (CCPA) 1956)).

Rather, the case law is clear that "[t]he specification need not contain an example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without undue experimentation. *In re Borkowski,* 422 F.2d 904, 908, 164 USPQ 642, 645

(CCPA 1970)." Applying this standard to the present case, Applicants assert that experimental data for each indication to be treated is not required. Rather, because the specification provides extensive enabling details such that one skilled in the art would be able to readily practice the claimed invention in the absence of undue experimentation, Applicants submit that, even if the specification did not contain *any* working examples (which the Office has acknowledged not to be the present case), the present specification would still be in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph. Thus, this rejection should be withdrawn.

Based on the foregoing, Applicants respectfully request that this rejection be withdrawn.

Written Description

Claims 23, 28, and 48-67 are rejected for lack of written description for two asserted grounds. First, the Office states that the terms "polypeptide encoded by a polynucleotide that hybridizes at high stringency..." in claims 23 and 28 and "wherein said mammalian subject is a human" in claims 54 do not find support in the specification. Second, the Office asserts that the specification, while providing adequate support for SEQ ID NOs: 3 and 4, does not describe variants of such sequences.

Turning to the first ground of rejection, Applicants note that the terms "polypeptide encoded by a polynucleotide that hybridizes at high stringency..." no longer appear in claims 23 and 28, therefore rendering this aspect of the rejection moot. Applicants have also cancelled claim 54. In view of the foregoing, Applicants respectfully request that the first ground of the § 112, first paragraph rejection be withdrawn.

In asserting that the specification does not provide adequately describe polynucleotide sequences hybridizing at high stringency to the complement of SEQ ID NO: 3 that encodes SEQ ID NO: 4, the Office states that one skilled in the art would not recognize the claimed polypeptides absent the recitation of clear hybridization conditions. As amended, claims 23 and 28, from which the other rejected claims depend, are now directed to polynucleotides encoded by polynucleotides that hybridize at 65^0C in 0.1x SSC to the sequence of SEQ ID NO: 3. Based on the recitation of such hybridization conditions, one skilled in the art would immediately recognize what is claimed and Applicants therefore respectfully request that the § 112, first paragraph rejection be withdrawn.

Rejections under 35 U.S.C. 112, second paragraph

Claims 23 and 28 are rejected for recitation of the terms "...polypeptide encoded by a polynucleotide that hybridizes at high stringency...," which the Office finds indefinite. As requested by the Office, claims 23 and 28 have been amended to include specific hybridization conditions. This rejection may therefore be withdrawn.

Applicants submit that the application is in condition for allowance, and such action is respectfully requested. A petition for an extension of time accompanies this response. Please charge any payments or credit any overpayments of the same to Deposit Account No. 50-0311, reference 22058-514 NATL. Should any questions or issues arise concerning the application, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,

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